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Director & State Health Officer

State of California—Health and Human Services Agency  
California Department of Public Health



EDMUND G. BROWN JR.  
Governor

December 19, 2012

TO: ALL INTERESTED PARTIES

SUBJECT: HEPATITIS C TESTING IN NON-HEALTH CARE SETTINGS, POLICIES AND PROTOCOLS FOR SITE SUPERVISORS AND TESTING COORDINATORS

As part of efforts to make hepatitis C virus (HCV) antibody testing widely available to all, California law now allows HIV test counselors, under specified conditions, to perform HCV tests classified as waived under the federal Clinical Laboratory Improvement Act (CLIA). The California Department of Public Health, Office of AIDS (CDPH/OA) offers the enclosed guidelines to assist local health departments and other community-based organizations who wish to employ trained, non-medical personnel to provide HCV rapid testing to their clients.

Federal and state regulations require that organizations intending to perform CLIA-waived tests must apply for and receive a CLIA Certificate of Waiver prior to beginning testing. For medical personnel listed in Business & Professions Code Section 1206.5 who are working within their scope of practice and who are permitted to perform CLIA-waived tests, there are no additional requirements beyond those listed by the manufacturer in the HCV test package insert.

Health & Safety (H&S) Code 120917 allows non-medical personnel who are OA-trained HIV test counselors to perform HCV rapid testing once they are trained in HCV rapid testing proficiency and integrated HIV/HCV counseling by OA or its agents. See pages 3-4 of the attached CDPH HCV rapid testing guidelines for more information.

In addition to the above requirement, the law requires test counselors to give clients who receive HCV antibody testing the following information:

- Test results that are reactive mean that the client has had HCV infection in the past and may or may not have HCV infection now;
- Additional testing is needed to determine whether the client has HCV now.

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The law also requires that:

- “Indeterminate” or “positive” (i.e., reactive HCV antibody) test results must be referred to a licensed health care provider whose scope of practice includes the authority to refer patients for laboratory testing for further evaluation.

OA and the CDPH Office of Viral Hepatitis Prevention will host a webinar to review the requirements for delivering HCV rapid test results in February. A meeting invitation will be sent out before that time, and the webinar will be recorded and posted on both the OA and OVHP websites. OA quality assurance guidelines for HCV testing in non-healthcare settings will be distributed soon and posted online.

Please see the attached guidelines for additional information, including contact information for CDPH technical assistance.

Sincerely,

A handwritten signature in black ink, appearing to read "Brian D. Lew, M.A.", with a stylized flourish at the end.

Brian D. Lew, M.A.,  
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HIV Prevention Branch Chief  
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California Department of Public Health

Enclosure

cc: See next page

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